AUG - 1 2001

Cordis Europa N.V. ,
a Johnson & Johnson company

Special 510(k) Premarket Notification

K012056

Attachment 1

Summary of Safety and Effectiveness

Submitter:

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Date prepared

29 June 2001.

General provisions

Trade name: Cordis **PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM™ .018" Delivery System.**

Common Name: Biliary stent and accessories

Classification Name: 21 CFR 876.5010 Biliary Catheter.

Device Classification

Class II.

Name of predicate device(s)

- Cordis BX Transhepatic Biliary Stent and Delivery System (reference K001258)
- Cordis **PALMAZ CORINTHIAN IQ** Transhepatic Biliary Stent and Delivery System (ref. K992755 and K994156)
- Cordis **SLALOM** PTA Balloon Catheter (ref. K003159)

Performance standards

Performance standards have not been established for this device by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Device Description

The **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM** .018" Delivery System is a balloon-expandable, stainless steel stent that is provided premounted upon the Cordis **SLALOM** balloon catheter (ref. K003159). The stent is provided in four nominal, unexpanded stent lengths: 12, 15, 18 & 24 mm. The stent is designed for expansion to diameters from 3 to 6 mm, depending on the diameter of the associated balloon upon which it is mounted.

The **PALMAZ GENESIS** Transhepatic Biliary stent on **SLALOM** .018" Delivery System is provided sterile and is intended for single use only.

Intended Use

The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM** .018" Delivery System is intended for use in the palliation of malignant neoplasms in the biliary tree.

Performance Data

The safety and effectiveness of the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM** .018" Delivery System has been demonstrated via data collected from non-clinical design verification tests and analyses.

Biocompatibility

All materials used in the **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM** .018" Delivery System are biocompatible.

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Fedral Food, Drug and Cosmetic Act releted to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2001

Cordis Europa, N.V.
c/o Mr. Chuck Ryan, RAC
Manager, Regulatory Affairs
Cordis Corporation
7 Powder Horn Drive
WARREN NJ 07059

Re: K012056
Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent
on SLALOM™ .018" Delivery System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: June 29, 2001
Received: July 2, 2001

Dear Mr. Ryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012056

Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM™ .018" Delivery System

FDA's Statement of the Indications For Use for device:

The Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM™ .018" Delivery System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012056